

REMARKS

The application includes claims 1, 2, 5, 7 - 11, 13 - 17, and 19 - 32. Claims 2, 5, 24-29, 31, and 32 are currently amended; all the other claims were previously presented.

Claim objections

Claims 2, 5, 24-29, 31, and 32 were rejected "because the term "comprises" opens up these claims to include other conditions and risk factors in the dependent claims. Thus, the term "comprises" as used in these objected claims is suggested to be changed to -is-".

The objected claims are now amended as suggested by the examiner, and further amended to use the language "one of said at least one risk factor is", to improve the clarity of the claim.

Claims 13 and 14 were objected as being duplicates of claim 11, and claims 19 and 20 were objected for being duplicates of claim 17. As the Examiner correctly mentioned in the Office Action, this objection would be proper only if claim 11 or 13 were allowed. As these claims are not yet allowed, the objection is premature.

Nevertheless, to obviate the need to discuss these objections in the future, it is respectfully submitted that claim 11 depends on claim 1, while claims 13 and 14 depend on claims 7 and 8, respectively. Therefore, the objected claims are distinct from claim 11 at least as claims 7 and 8 are distinct from claim 1.

Similarly, claim 17 depends on claim 1, while claims 19 and 20 depend on claims 7 and 8, respectively, and the objected claims are distinct from claim 13 at least as claims 7 and 8 are distinct from claim 1.

Claim rejections

35 USC 35 § 112

Claims 1-2, 5, 7-8, 11, 13, 14, 17, 19, 20, and 26 were rejected under Section 112, second paragraph, because "the component "high concentration" is vague and indefinite as to what the component is per se." It is respectfully submitted that there are medical standards defining for each of the substances recited in the claims, what concentration is "high". Therefore, the term "high concentration" is clear to a skilled person.

Furthermore, the term "high concentration" is used in the claims for indicating risk factors, and a skilled person knows exactly when a concentration of any of the substances recited in the claims is considered to be high enough to become a risk factor.

Therefore, the component recited as "high concentration" for these commonly measured blood factors is not vague at all, and the claims are definite.

35 USC 35 § 103

All the pending claims were rejected as being obvious over Fuhrman et al in view of Sha et al (US 6,280,776).

Fuhrman et al describes lowering LDL susceptibility to oxidation by administering a water-insoluble ethanolic extract of licorice, which is free of glycyrrhizinic acid. Sha et al describes treating some certain risk factors or conditions with a water-soluble licorice extract. The Examiner admits that the extracts are different, but states that it would have been obvious to replace the licorice extract disclosed by Sha et al with that disclosed by Fuhrman et al in order to minimize LDL oxidation in Sha et al.

It is respectfully submitted, that a skilled person knows that substances that are water insoluble (for instance, Fuhrman's extract) are not present in extracts that are water soluble (For instance, Sha's extract.). If they were, the extract would not be water soluble.

Therefore, a skilled person reading Fuhrman et al should have expected that the replacement suggested by the Examiner will indeed help in reducing LDL oxidation, but on account of achieving the results taught by Sha et al.

This is even strengthened by the teachings of Sha et al, that the licorice extract they use has glycyrrhizine as a major component, known to be medicinally beneficial. Glyzyrrhizine (which is misspelled by Sha et al) is a chemical synonym to glycyrrhizinic acid, of which Fuhrman's extract is free. In this context, the Examiner is referred to column 3 lines 40-48:

Glycyrricine, which is a main component of Licorice root, has been known to improve several symptoms with liver injuries and to elevate the serum transaminase by the double blind examination.

Further, glycyrricine has been shown to protect CCl₄-induced liver injury (Matsushima, Rinsho & Kenkyu, vol. 56(10), 345-(3461)(1979)).

Furthermore, there is practically no expectation that the same root would contain water soluble and water insoluble components that are each independently effective to treat the same

conditions. Once Sha et al showed that licorice root contains water-soluble components that are effective for treating certain conditions, it is so far from being expected that water soluble components of licorice are effective to treat the same conditions, that in fact, a skilled person reading Sha et al would be less motivated to use Fuhrman's extract for treating Sha's conditions, than would be a skilled person ignorant of the teachings of Sha et al. In other words, Sha et al teach against the replacement suggested by the Examiner.

In view of the above explanations, no *prima facie* case of obviousness was made, and the claimed invention is patentable over the cited art.

Respectfully submitted,



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July 9, 2007

Encls:

Petition for Extension of Time for One (1) Month
Request for Continued Examination (RCE)